THE EFFICACY OF ACTION POTENTIAL THERAPY, AS WELL AS THE RELATIVE EFFECTIVENESS OF TWO DIFFERENT ACTION POTENTIAL THERAPY ELECTRODE PLACEMENTS (ABDOMINAL VERSUS PARASPINAL) IN THE MANAGEMENT OF IRRITABLE BOWEL SYNDROME

BY

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I, Ivor von Senger, do hereby declare that this dissertation represents my own work in both conception and execution.

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For LOM, a special friend who will be remembered always

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To Lom, a special friend who will be remembered always.

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ABSTRACT

The aim of this placebo-controlled trial was to investigate the efficacy of action potential therapy (APT) versus placebo, and the relative effectiveness of abdominal versus paraspinal electrode placement, in the treatment of Irritable Bowel Syndrome (IBS).

Convenience sampling was used to recruit sixty patients with IBS from the community. These patients were randomly divided into four groups (A, B, C and D). Each group consisted of 15 patients, aged between 20 and 69 years. Patients attended five consultations over three weeks. Treatment was given with either active or placebo APT during the first four consultations. The fifth consultation was for data collection only.

Patients in group A and C both received active APT. In group A, the electrodes were placed over the abdomen, while in group C the electrodes were placed paraspinally. Patients in group B and D both received placebo APT using a placebo APT device. In group B, the electrodes were placed over the abdomen, while in group D, the electrodes were placed paraspinally.

The measures of efficacy were the IBS Quality of Life Questionnaire (IBS-QOL), the Short-form McGill Pain Questionnaire (SF-MPQ) and the Life Line Stress Questionnaire (LL-SQ). Using these questionnaires, data was collected at the 1st, 3rd and 5th consultations for each participant. The data was then analysed using the SPSS package. Assessment of intra-group and inter-group change was performed using Friedman's T-test and the Mann-Whitney U-Tests respectively. Analysis was performed at the 95% confidence level.

Patients in all four groups showed an improvement in quality of life (measured by the IBS-QOL), as well as in the perceived quantity of pain experienced (measured by the SF-MPQ), between initial and final consultations. As regards the patients' levels of stress (measured by the LL-SQ), there was no statistically significant improvement in any of the four groups between initial and final consultations.

Inter-group comparison of the data showed a higher perceived quantity of pain in the active, paraspinally placed APT group (group C) at the first consultation when compared to both the

placebo, paraspinally placed APT group (group D) and the active, abdominally placed APT group (group A). There was no more significant difference at the final consultation between these groups, which suggests that the patients' perception of quantity of pain improved to a greater extent in group C than in groups A or D. However, definitive conclusions are hard to be made from this because the groups were different at baseline level.

Otherwise, statistical inter-group comparison showed no other significant differences between the two groups for any of the subjective measures at any stage during the trial period.

From these results, it is impossible to conclude that APT is more effective than placebo, or that there is a difference between abdominally placed, and paraspinally placed APT, in the management of IBS. However, in order to facilitate the clinical relevance of trials of this nature, it is suggested that more attention be paid to the limitations of this study, some of which were measures of efficacy, sample size, and blinding.

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DEFINITION OF TERMS

Action Potential Current A high-frequency electrical current that simulates or mimics the naturally occuring action potential in a neuron. It is applied to the affected area via electrodes and is associated with pain alleviation, enhanced joint flexibility, a decrease in oedema due to improved circulation and possibly reduced inflammation (Berger 1999).

Borborygmus A rumbling noise caused by the propulsion of gas through the intestines.

Postprandial After a meal.

Subjective Clinical Findings Those findings obtained from the patient's perception of severity of symptoms, as per the Short-Form McGill Pain Questionnaire, the IBS-Quality-Of-Life Questionnaire and the Life-Line Stress Questionnaire.

Transcutaneous Electrical Nerve Stimulation (TENS) A form of low-frequency current electrotherapy that uses an asymmetrical, biphasic modified square wave with a zero net direct current component.

CHAPTER ONE

1.0 INTRODUCTION

1.1 The problem and its setting

Irritable Bowel Syndrome (IBS) is the most common diagnosis in gastroenterologists' practice, accounting for 28% of all their patients (Mitchell and Drossman, 1987). According to the American Gastroenterological Association (1997), IBS affects 14%-24% of women and 5%-19% of men in the US, most European countries, China and Japan. Walker and Segal (1983) found the prevalence of IBS in South Africa to be similar to that of prosperous western countries, though less so in the poorer socio-economic groups, especially those living traditional lifestyles.

It is estimated that only 10% to 25% of patients with IBS seek medical care. The illness nevertheless has an enormous economic impact. In the U.S. alone, the economic impact is estimated at $ 25 billion annually through direct health care costs and indirect costs of absenteeism from work (absenteeism among patients suffering from IBS is roughly equivalent to that among those suffering from the common cold)(Camilleri and Williams, 2000).

IBS is characterized by symptoms of intermittent diarrhoea, abdominal colic relieved by bowel action and a 'bloated' feeling –due to altered gut motility. Although the symptoms of IBS have a physiological basis, no physiological mechanism unique to IBS has been identified. Numerous theories have developed regarding the pathophysiology of the disease. It is now believed to result from dysregulation of intestinal motor, sensory and central nervous system functions (American Gastroenterological Association, 1997). IBS varies in severity from trivial to incapacitating.

There are two types of IBS grouped according to the signs and symptoms: The first is the spastic colon type where bowel movements are variable. Most patients have pain of colonic origin over one or more areas of the colon associated with periodic constipation or diarrhoea. The second group of IBS patients primarily manifest painless diarrhoea, usually urgent, precipitous diarrhoea that occurs immediately upon rising or, more typically, during or immediately after a meal (Berkow 1992: 842).

Zietsman (1997) stated that, as yet, there is no complete cure for IBS as there is no known organic cause. However, he acknowledged that certain drugs can alleviate specific symptoms of the syndrome. Today it is no longer acceptable practice to diagnose the condition and to discharge the patients on high fiber diets, particularly because it can make the situation worse (Francis and Whorwell 1997). Symptomatic treatment includes supplementing fiber to achieve a total intake of up to 30g only in those IBS patients suffering from constipation. Those suffering from diarrhoea are prescribed loperamide or other opioids, and those suffering predominantly from pain are prescribed low-dose antidepressants or antispasmodics (Camilleri, 2001).

Sylvester, Kendall and Lennard-Jones (1986) demonstrated treatment of IBS using electrotherapy. They found transcutaneous electrical nerve stimulation (TENS) to be effective in reducing the symptoms of IBS, although this study did not make use of a consistent site of electrode placement.

A new form of electrotherapy, action potential therapy (APT), which is a low intensity, high frequency current, has recently been developed, that has shown anecdotal efficacy in treating IBS (Schmidt, 2000).

The effect of APT on pain-regulatory and anxiolytic hormones circulating in the blood was demonstrated by De Wet and Oosthuizen (1999). The neurohormones that were elevated in comparison to the control group were leucine enkephalin, and melatonin, both of which have been found to be lower in blood samples of patients with IBS than controls (Roberts-Thompson, et al. 1988).

There is uncertainty in the literature regarding the most effective site of electrode placement for IBS. The study by Kendall and Jones seemed to indicate that the most effective sites were over the abdomen (71% of those that responded to TENS treatment), as well as paraspinally (21% of those that responded to TENS treatment). However, De Wet and Oosthuizen (1999) demonstrated that paraspinal placement over the low back increased the level of pain regulatory and anxiolytic neurohormones in the blood, providing support for paraspinal electrode placement.

It is therefore uncertain whether the placement of electrodes has any pivotal effect in the treatment of IBS. A thorough literature review revealed no proven physiological relationship

between skin on the anterior abdominal wall and the gut, but it is possible that currents extend below the skin to the viscera. Comparing abdominal to paraspinal placement of electrodes would aid significantly in clarifying whether the modality is effective locally through reflex pain inhibition or indirectly through centrally mediated processes.

Although anecdotal evidence suggests clinical efficacy in the treatment of IBS, there is a scarcity of published literature on action potential therapy.

It is thus the intention of this placebo-controlled trial to investigate the efficacy of action potential therapy versus placebo, and the relative effect of abdominal versus paraspinal electrode placement, in the treatment of Irritable Bowel Syndrome.

1.2 Aims and Objectives of the study.

The aim of this study is to determine the efficacy of action potential therapy, as well as the relative effect of two different action potential therapy electrode placements (abdominal versus paraspinal) in the management of Irritable Bowel Syndrome.

The first objective was to determine the efficacy of action potential therapy versus placebo in the management of Irritable Bowel Syndrome.

The second objective was to compare the relative effectiveness of abdominal versus paraspinal electrode placement of action potential therapy in the management of Irritable Bowel Syndrome.

1.3 Benefits of the study

This study should add to the pool of knowledge with regards to more effective management of IBS by investigating trends as found by authors such as Sylvester, Kendall and Lennard-Jones (1986).

A well-designed randomised clinical trial could serve as a 'blue print' for future studies to be fashioned, taking into account the methodological principles proposed by the author, to attain results that are conclusive as well as repeatable.

The author hopes that this investigation will serve to inspire those affected to search for answers to the many questions that still elude us regarding the treatment of IBS.

CHAPTER TWO

2.0 REVIEW OF THE RELATED LITERATURE

2.1 Introduction

The following is an overview of the related literature concerned with clinical trials on IBS including the use of APT in the treatment of IBS. The theoretical basis for the action and effects of APT as well as the basic clinical, etiological and epidemiological aspects will be presented.

2.2 Definition and Classification

Beginning in the late 1970s, investigators attempted to define IBS using symptom-based criteria derived from epidemiological investigations. The Manning criteria (Manning, et al. 1978) have been most widely used in clinical research, and several others have also existed. Validation of these criteria has been difficult as there are no biological markers to define this disorder. As a result, investigators developed a consensus definition and criteria, known as the Rome criteria (Drossman, et al. 1999).

IBS is a "combination of chronic or recurrent gastrointestinal symptoms not explained by structural or biochemical abnormalities," which is "attributed to the intestines and associated with symptoms of pain and disturbed defecation and/or symptoms of bloatedness and distension" (Drossman, et al. 1994).

Table 2.1. Diagnostic criteria for IBS

Rome Criteria (Drossman, et al. 1999)

At least 3 months of continuous or recurrent symptoms of the following:

Abdominal pain or discomfort,
- Relieved with defecation, or
- Associated with a change in frequency of stool, or
- Associated with a change in consistency of stool.

Two or more of the following, on at least one-fourth of occasions or days:

- Altered stool frequency (for research purposes, "altered" may be defined as more than three bowel movements each day or fewer than three bowel movements each week);
- Altered stool form (lumpy and hard, or loose and watery);
- Altered stool passage (straining, urgency or a feeling of incomplete evaluation);
- Passage of mucus, or
- Bloating or a feeling of abdominal distention

Manning Criteria (Manning, et al. 1978)

Abdominal pain relieved by defecation,
Looser stools with onset of pain,
More frequent stools with onset of pain,
Abdominal distension,
Passage of mucus in stools,
Sensation of Incomplete evacuation

2.3 Epidemiology

The estimated prevalence of IBS varies from study to study. This is believed to be a result of the diversity of definitional criteria and differences in the specific questions used to elicit the information. In general, studies requiring only two Manning criteria gave higher prevalence estimates than those requiring more stringent criteria, such as three Manning symptoms or the Rome criteria, which are most restrictive (see table 2.2). In Britain and the United States, IBS affects 14%-24% of women and 5%-19% of men (American Gastroenterological Association, 1997).

Table 2.2 Epidemiological Studies of IBS in American and European Adults (American Gastroenterological Association, 1997).

Source	Group characteristics	N	Age (yr)	Diagnostic criteria	% IBS		
					Total	Women	Men
Talley, et al.	White=99%	835	50(range 30-64)	≥3 Manning	12.8	13.6	12.1
Heaton, et al	English Urban White=99%	1896	25-69 (Women) 40-69 (Men)	≥3 Manning	9.5	13	5
Jones and Lydeyard	Mostly White	1620	20-90	≥2 Manning	21.6	24.3	18.7
Drossman, et al.	U.S Householder White=95% Women=51%	5430	49±16	Rome	9.4	14.5	7.7
Kay, et al.	Copenhagen Sex stratified	3608	Age stratified	Altered bowel habits & pain relieved by defecation	6.6	7.7	5.6
Zuckerman, et al.	White=36% Hispanic=64% Women=66%	950	30.5+-9.3	Altered bowel habits and abdominal pain, constipation, or diarrhoea	16.9	21.7	7.1
Taub, et al.	College students Black=27% Women=62%	1344	21.2+- 5.6	≥3 Manning	21.8	26.5	13.9

Table 2.2 seems to indicate that IBS is more prevalent in women than in men. The prevalence also seems similar in whites and blacks (in the USA) but may be lower in Hispanics, and there is also a decrease in reporting frequency among older subjects in 4 of the 5 studies that included age-stratified groups.

2.4. Pathophysiology of IBS

According to the American Gastroenterological Association (1997), no physiological mechanism unique to IBS has been identified. They believe that the same physiological mechanisms are responsible for abdominal pain and altered bowel habits in people without IBS, and that all individuals can experience these symptoms at some time in their lives. They usually occur in response to a disruption in the function of the GI tract from an infection, dietary indiscretions, lifestyle changes or psychological stress. For example, in a survey of college students and hospital employees, 71% reported that stresses affect their bowel pattern, and 54% reported that stress led to abdominal pain or discomfort (Drossman, et al. 1982)

2.4.1 Abnormal Motility in Patients with IBS

The American Gastroenterological Association (1997) reviewed the vast literature with regards to abnormal motility. Their conclusions were:

1. The types of motility patterns seen in the colon and small intestine in patients with IBS are similar to the contractions seen in healthy persons.
2. There is no consensus on the patterns of motility responsible for diarrhoea and constipation.
3 There are some patients with diarrhoea-predominant IBS who have accelerated transit in the small bowel and/or colon.
4. There are some patients with constipation-predominant IBS who have slowed or delayed transit.

People with IBS have increased motility in response to environmental or enteric stimuli. Factors such as psychological stress, meals, balloon inflation, and cholecystokinin lead to an exaggerated intestinal motor response. There is also epidemiological evidence that IBS symptoms may commence after acute infectious diarrhoea.

2.4.2 Enhanced Visceral Sensitivity

The lack of correlation between symptoms and motor disturbances led to studies on visceral sensitivity (or hyperalgesia), a concept that has changed our understanding of symptom generation in IBS. Interest in this concept began with balloon distension studies of the sigmoid colon, and subsequently of the ileum and colorectum. These showed that a significant number of patients with IBS experience awareness of distension and painful symptoms at pressures and volumes that are significantly lower than control subjects (Whitehead, et al. 1990).

2.4.3. Dietary Factors

Nanda, et al. (1989), in a study involving two hundred patients, found that food intolerance was implicated in roughly half of patients with IBS. The foods most commonly incriminated in this study were dairy products (40.7%) and grains (39.4%).

There is some controversy as to whether some of the symptoms experienced by IBS patients may be because of a lack of dietary fibre or the consumption of fibre-depleted food. A study on the efficacy of bran was done in a double-blind, placebo-controlled, crossover trial on twenty-eight IBS patients over three months. The data from this trial suggest that any beneficial effects of bran were due to placebo response, although the small sample size used precludes any accurate assessment (Lucey, et al. 1987).

Another trial of similar design using eighty patients with IBS found that the bulking agent, ispaghula, significantly improves overall well being and favourably affects bowel habits and transit time for patients with constipation, but is no more effective than placebo in relieving abdominal pain and distension (Prior and Whorwell, 1987).

Some patients with IBS also have carbohydrate intolerance, which may contribute to the symptoms of IBS. Intolerance of sugars is partly determined by the ethnicity of the patient. Lactose intolerance has a higher prevalence among Hispanic and black patients, whereas fructose and sorbitol intolerance are more prevalent among people of Northern European extraction (Rumessen and Gudmand-Hoyer, 1987).

2.4.4 Infectious Diarrhoea

According to Neal, Hebden and Spiller (1997), infectious diarrhoea precedes the onset of IBS symptoms in 7%-30% of patients. It is believed that patients with prior *Campylobacter* enteritis are more susceptible to the onset of IBS than other strains of bacteria.

The mechanism of development of IBS from infectious diarrhoea remains controversial. Gwee, et al. (1999) hypothesised that microscopic inflammatory changes such as infiltration of the enteric nervous system contribute to the development of IBS. It is believed that a previous infectious episode could induce a physiologic response, causing persistent symptoms, even once any trace of a causative toxin has disappeared.

2.4.5 Psychosocial Factors

Although psychological stress can affect gastrointestinal function and produce symptoms in everyone, it does so to a greater degree in patients with IBS. According to Drossman, et al. (1994), patients with IBS have greater psychological stress than healthy persons or persons that do not seek health care. Psychosocial factors are neither diagnostic of IBS nor the cause, but they can influence the way the illness is experienced, who will seek medical help and the eventual clinical outcome.

The implications are therefore that for many patients, treatment of the bowel symptoms alone may be insufficient to produce clinical improvement and that the physician should also address and attempt to modify any contributing psychosocial factors.

2.5 Clinical manifestation

According to Francis and Whorwell (1997), the most common symptoms of IBS are the following:

- Varying degrees of abdominal pain or discomfort
- Abnormal bowel habit
- Abdominal distension or bloating
- Feelings of incomplete evacuation
- Mucus per rectum

Symptoms are intermittent with variable periods of remission.

In addition, patients with IBS may experience a variety of non-colonic symptoms including the following:

- Dysphagia
- Heartburn
- Dyspepsia
- Headaches (>1 week)
- Back pain
- Bad breath

- Urinary frequency
- Urgency of micturition

Maxton, Morris and Whorwell (1991) demonstrated that a more accurate and confident diagnosis of IBS can be made using these 'non-colonic' symptoms (as an adjunct to conventional methods). In a study using a total of 402 subjects attending a gastroenterology outpatient department, the prevalence of 'non-colonic' symptoms in IBS was compared to five organic diseases of the bowel, namely, crohns disease, ulcerative colitis, peptic ulceration, gall stones and reflux esophagitis. The findings confirmed a substantial higher prevalence of these symptoms in IBS.

2.6 Diagnosis

The diagnosis of IBS is based on the identification of symptoms consistent with the syndrome and the exclusion of organic diseases that have similar clinical presentation.

The first step is a careful assessment of the patient's symptoms. The Rome criteria, as described in Table 2.1, have become widely accepted as the preferred method to raise the clinical suspicion of IBS (Drossman, et al. 1999). The absence of rectal bleeding is helpful in excluding organic disease (Thompson, et al. 1989). A thorough physical examination and a limited series of initial investigations are needed to exclude organic structural, metabolic, or infectious diseases. These include haematology and chemistry tests, erythrocyte sedimentation rate, stool examination for occult blood, ova, and parasites (in those with diarrhoea predominance); flexible sigmoidoscopy; and, in those over 40 years of age or with family history of colon polyps or cancer, a complete colonic evaluation (Camilleri, 2001).

Since IBS is the most common reason for referral to gastroenterologists, a diagnosis based on exclusion may result in large numbers of expensive, uncomfortable and often dangerous tests. Francis and Whorwell (1997) therefore feel that general practitioners should try to diagnose IBS confidently and positively with minimal investigation. They believe that investigation can initially be limited to a full blood count, erythrocyte sedimentation rate and sigmoidoscopy.

2.7 Differential Diagnosis

In making an accurate differential diagnosis, quality, location, and timing of symptoms must be considered. Pain mostly in the epigastric region: biliary tract disease, peptic ulcer, intestinal ischemia, and carcinoma of the stomach or pancreas are likely differentials. IBS mainly in the lower abdomen: diverticular disease, inflammatory bowel disease, and carcinoma of the colon must be considered. Postprandial pain accompanied by bloating, nausea, and vomiting suggest gastroparesis or partial obstruction. If diarrhoea is the major complaint: lactose deficiency, laxative abuse, malabsorbtion, hyperthyroidism, inflammatory bowel disease and infectious diarrhoea. Constipation as the main complaint: side effects of many different drugs such as anticholinergic, antihypertensive, and antidepressants. Endocrinopathies must also be considered (Kelley, 1997:710).

2.8 Therapies for IBS.

Because physiological and psychological factors together affect symptom type and severity, it is important to consider both in planning treatment. Worry and anxiety can exacerbate the symptoms of IBS, thus an effective patient-physician relationship is essential for successful management of this disorder (Francis and Whorwell, 1997).

Most IBS patients have only mild symptoms, maintain normal daily functions, and are not high health care users. They usually respond to a general treatment approach involving patient education, reassurance and dietary/lifestyle changes. A smaller proportion of patients have moderate to severe symptoms that are usually intermittent, but sometimes disabling. Allopathic treatments include gut-acting pharmocological agents (e.g. anticholinergics, antidiarrhoeals, etc). In some cases, psychological treatments, including antidepressant medication are necessary (American Gastroenterological Association, 1997).

Realistic treatment goals should be set and the patient must understand that although a miraculous cure is unlikely, considerable symptomatic relief can be obtained (Francis and Whorwell, 1997).

2.8.1 Role of Fibre in Treatment of IBS

Increased dietary fibre is frequently recommended for patients with constipation-predominant IBS, even though, as a group, these patients do not consume less dietary fibre than control subjects (Jarrett, et al. 1994). According to the American Gastroenterological Association (1997), the use of fibre is based on evidence that it will accomplish the following :

1. Decrease gut transit time, which may alleviate constipation ,
2. Decrease intracolonic pressures, which could reduce pain, because it is recognised that wall tension is one of the factors that contributes to visceral pain (Distrutti, et al. 1999).
3. Dilute bile salts, which could indirectly reduce contractile activity in the colon.

However, Cook, et al. (1990) reviewed previous trials involving the role of fibre in treatment of IBS, and found the results to be inconclusive. Their reasoning was as follows:

- Four of the nine previous studies of fibre therapy in IBS showed benefit and five showed no benefit.
- All of these studies suffered from one or more methodological shortcomings. Examples of these were: inadequate placebo control; lack of a double-blind design; concurrent use of other gastrointestinally active drugs, and a lack of objective symptom assessment.

This study also showed no significant difference between the treatment group and placebo on reducing the symptoms of IBS. The authors attempted to overcome shortcomings identified in previous investigations, but over-elimination of unsuitable candidates resulted in the sample size being too small.

2.8.2 Loperamide and Antidiarrhoeal Agents in IBS.

Diarrhoea-predominant IBS is associated with acceleration of small bowel and proximal colonic transit. Loperamide, a synthetic opioid, decreases intestinal transit, enhances intestinal water and ion absorption, and increases anal sphincter tone at rest. These physiologic actions seem to explain the improvement in diarrhoea, urgency, and faecal soiling observed in patients with IBS when this drug is taken (Cann, et al. 1984).

In a double-blind placebo-controlled trial, Efskind, Bernklev and Vatn (1994) investigated the efficacy of loperamide on 90 IBS patients suffering predominantly from diarrhoea. The trial was well constructed in that it had an initial 3 week baseline period (in which the subjects were monitored while receiving no treatment), followed by five weeks of treatment. While stool consistency and frequency were both significantly reduced in the treatment group, there were no significant differences in the intensity of pain related to meals, incomplete defecation, bloating or borborygmi. Intensity of pain during the night was incidentally higher in the treatment group than in the placebo group.

Because it does not traverse the blood-brain barrier, loperamide is generally preferred to other opiates such as diphenoxylate, codeine, or other narcotics for treating patients with IBS who have predominant diarrhoea and/or incontinence. Clinically, loperamide can also be used to reduce urgency associated with a colonic response after a meal or as a means of improving bowel control at times of stress or other colonic stimuli (e.g. exercise, social gatherings). One of the drawbacks of opioids is the tendency to induce constipation (Efskind, Bernklev and Vatn, 1994). Loperamide also contains atropine which may induce adverse effects that may be worrisome in the elderly, e.g. bladder dysfunction, glaucoma, and tachycardia (Cann, et al. 1984).

2.8.3 Smooth Muscle Relaxants

The most frequent medications used for the treatment of IBS pain and bloating are the antispasmodics. Included in this category are the antimuscarinic agents and calcium channel blockers. The rationale is based on relaxing smooth muscle and reducing gastrointestinal motility. These agents should be used only for acute exacerbation of postprandial pain as they rapidly lose efficacy in chronic treatment (Drossman, Whitehead and Camilleri, 1997).

Randomised, double-blind, placebo-controlled studies of at least two weeks' duration show that abdominal pain was relieved in 68% (mean range 23%-87%) for active antispasmodics and 31% (mean range, 22%-66%) for placebo (Camilleri and Choi, 1997). However, as noted by Klein (1988), the field of antispasmodic and anticholinergic therapy in IBS is beset with methodological problems. The broad spectrum of subgroups of the trials, differing measures of efficacy, high rates of patient drop-out (up to 60% before follow up), and high placebo response rates (as high as 69%) are examples of these problems.

In clinical practice, antispasmodics and anticholinergic agents are best used on an as-needed basis up to two times per day for acute attacks of pain and bloating (Camilleri, 2001).

2.8.4. Antidepressants

Antidepressants, either the tricyclic agents or serotonin reuptake inhibitors, are frequently used to treat patients with IBS, particularly those with more severe symptoms, impaired daily function, and associated depression or panic attacks. Initially their use was based on the fact that a high proportion of patients with IBS reported significant depression. However, it is now recognised that the antidepressants have analgesic as well as neuromodulatory properties (Clouse, 1994).

In most of the placebo-controlled trials, antidepressants decrease abdominal pain and depression, but they usually have no beneficial effect on stool frequency (American Gastroenterological Association, 1997).

2.8.5 Non-Drug Therapy

Hypnotherapy has shown that in addition to relieving the symptoms of IBS it is capable of profoundly improving the patient's quality of life and reducing absenteeism from work. Although it is relatively expensive to provide it might be a good long-term investment (Houghton, et al. 1996) Unfortunately, double-blinding of any research of this type is impossible.

Results from a study on the effectiveness of homeopathic simillimum treatment on IBS sufferers suggest that this form of treatment can significantly improve the symptoms of IBS. In this double-blind, placebo-controlled study, thirty patients were randomly divided into one of two groups and treated with either homeopathic remedy or placebo for a period of three months. A statistically significant difference was observed at the end of the research trial when homeopathic treatment was compared to placebo with regard to the patients' perception of their symptoms and clinical findings (Rademan, 1997)

Sylvester, Kendall and Lennard-Jones (1986) undertook treatment of IBS using transcutaneous electrical nerve stimulation (TENS). Of the 29 patients who completed this

study, 21 showed a moderate (overall 33-66% reduction in pain on the visual analogue scale) to good response (greater than 66% reduction in pain on the visual analogue scale), indicating a 72.4% response that lasted at least six months. Patients were assessed every two weeks for a period of six months. Weaknesses of this trial include the following: the visual analogue scale, as a single entity, is not a valid measure of illness severity in IBS (Sherber, et al. 2000); it did not include a placebo group; and researchers allowed the patients to take the TENS units home, allowing length and frequency of treatments, as well as machine settings of intensity and frequency, to vary greatly between individuals.

This study seemed to indicate that the most effective sites were over the abdomen (71% of those that responded to TENS treatment), as well as paraspinally (21% of those that responded to TENS treatment).

2.8.6 Action Potential Therapy

A new form of electrotherapy, action potential therapy (APT), which is a low intensity, high frequency current that stimulates action potentials in a neuron, has recently been developed.

APT currents have been found by Goldberg (2000) and Atkinson (2000) to be beneficial in treating acute and subacute painful conditions. These authors suggested the efficacy of action potential therapy on patellofemoral pain syndrome and mechanical low back pain respectively, in separate double-blinded placebo-controlled studies.

APT has also been found to have an effect on pain-regulatory and anxiolytic hormones circulating in the blood, by De Wet and Oosthuizen (1999), who conducted a double blind placebo-controlled study on 20 patients with chronic low back pain. Venous blood was extracted immediately before as well as sixty minutes after the onset of the therapy sessions, which were conducted consistently between 07h30 and 08h30, to lower the chance of alterations in circadian hormone secretions. The neurohormones mostly affected were leucine enkephalin, and melatonin (both of which were increased in the APT therapy group), and beta-endorphin (which was decreased in the APT group).

Melatonin acts as a very potent sedative, hypnotic and anxiolytic agent (Castroviejo, et al. 1992). Roberts-Thompson, et al. (1988) compared circadian rhythms of Melatonin in 14 IBS sufferers to the same number of controls, by measuring urinary excretion every 4 hours for a

period of 48 hours. This study established that circulating levels of melatonin are lower in patients with IBS than controls.

Beta-endorphins and leucine enkephalin modulate pain transmission at supra-spinal and spinal level respectively (Guyton, 1992: 360). The decrease in levels of beta-endorphins may contradict current thinking i.e. that APT increases serum levels of pain regulatory neurohormones. However, De Wet and Oosthuizen (1999) believe that APT disrupts afferent information regarding pain before it reaches the brain, which then releases less beta-endorphin in response to diminished levels of pain perceived.

Although anecdotal evidence suggests the clinical efficacy of APT in the treatment of IBS, there is a scarcity of published literature.

2.9 Summary

IBS is a common condition that is poorly understood. Although the exact aetiology remains controversial, there is a large and growing body of evidence that suggests that the cause may be of a neurological nature. Recent advances in the diagnostic criteria have been helpful in both the research and the clinic settings, but successful treatment remains largely elusive.

Anecdotal evidence and neurophysiological relationships suggest that APT may be of use in treating this condition, but scientific evidence is scarce. The aim of this dissertation was therefore to further explore these observations in order to help clarify the role that APT may play in the management of this condition.

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 INTRODUCTION

This single blind, placebo-controlled study investigated the efficacy of action potential therapy, as well as the relative effect of two different action potential therapy electrode placements (abdominal versus paraspinal) in the management of Irritable Bowel Syndrome.

3.2 PATIENT SELECTION

A sample size of 60 IBS patients was used. These patients were recruited from the local community by means of advertisements, posters or referrals. Patients responding to advertising were screened telephonically to assess whether or not they fulfilled the inclusion criteria.

3.3 INCLUSION AND EXCLUSION CRITERIA

Only patients who fulfilled the inclusion criteria (Table 3.1) were accepted into this study. This was determined at the initial consultation by the following procedure.

1) A detailed case history was taken (Appendix A) and a physical examination (Appendix B) was performed on each patient.

2) Patients were assessed according to the Rome Diagnoistic Criteria (Drossman, et al. 1995) (Appendix C).

3) The researcher then explained the nature and importance of the study and each patient was given the Patient Information Sheet (Appendix D) to read.

4) Each patient then signed the Informed Consent form (Appendix E).

Table 3.1: Inclusion and Exclusion Criteria:

Inclusion Criteria (Rome Criteria):

At least 3 months of continuous or recurrent symptoms of the following:
Abdominal pain or discomfort,

- Relieved with defecation, or
- Associated with a change in frequency of stool, or
- Associated with a change in consistency of stool.

Two or more of the following, on at least one-fourth of occasions or days:

- Altered stool frequency (for research purposes, "altered" may be defined as more than three bowel movements each day or fewer than three bowel movements each week);
- Altered stool form (lumpy and hard, or loose and watery);
- Altered stool passage (straining, urgency or a feeling of incomplete evaluation);
- Passage of mucus, or
- Bloating or a feeling of abdominal distention

Exclusion Criteria:

1. Only patients aged 21 to 50 years were accepted into this study.
2. Any patient with a systemic (e.g. Crohn's disease or ulcerative colitis) or local pathology (eg. Gastric ulcer; dysentry) was not included.
3. If any contra-indications to action potential therapy were suspected the patient was not included in the study. These include
   - Patients that use pacemakers.
   - Pregnant women were excluded from the study.
   - Patients that suffered from epileptic seizures.
   - Patients on anticoagulant medication.
   - Patients that had been diagnosed with any form of cancer.
   - Patients with any form of venous thrombosis.
4. Patients were asked not to take analgesics or receive any other treatment while participating in this study.
5. If patients fell ill they had to withdraw from the study, as illness (or use of medication) often alters the patients' pain threshold. However these patients' participation could be used for demographic purposes.

3.4 ALLOCATION OF THE SUBJECTS

Each patient was then allocated to one of four groups by random assignment. Sixty slips of paper (15 of each of the four treatment protocols) were randomly drawn to plan the sequence of treatments in the study. The first 15 slips read group A, the next 15 read group B, etc. If, for example the 25th piece of paper chosen out of a hat indicated group B, the 25th patient was treated in the manner allocated to that group.

3.5 TREATMENT INTERVENTIONS

Subjects in Group A and B had the procedure explained to them and were treated with APT placed over the abdomen according to Berger (1999:136). The superior two electrodes were placed at the inferior border of the costal margin, at the attachment of the 10th rib to the costal cartilage, and the inferior two electrodes were placed below the umbilicus just medial to the two anterior superior iliac spines. The subjects in group C and D had the procedure explained to them and were treated with APT paraspinally according to de Wet and Oosthuizen (1999). The superior two electrodes were placed lateral to the spinous process of the eighth thoracic vertebra, at the lateral border of the erector spinae muscle, the inferior two electrodes were placed just lateral to the posterior superior iliac spines.

The patients were treated using two action potential therapy units, unit 1 and unit 2. Groups A and C received treatment with unit 1 while groups B and D received treatment with unit 2. One of the units was a placebo device while the other was a functioning unit. The researcher was blinded as to which of the units was functional. Patients in both groups were advised that the treatment may or may not be subliminal i.e. a sensation may or may not be evident.

The experimental groups received APT for eight minutes at a current intensity of 0-2 milliamperes, and a positive wave pulse with exponential decay, in accordance with the methodology outlined by Goldberg (2000) and Atkinson (2000). Patients in all 4 groups attended 5 consultations. They received APT during the first 4 consultations (which took place within 2 weeks), while the 5th consultation (held 1 week after the 4th consultation) was for data collection only. Data was also collected at the 1st consultation, before the 1st treatment, and at the 3rd consultation, before the 3rd treatment.

3.6 METHOD OF MEASUREMENT

Due to the fact that there are no established objective physiological markers for IBS (Wingate 1990: 17), only subjective measures were used.

The measures of efficacy were

a) The IBS Quality Of Life (IBS-QOL) Questionnaire (Drossman, et al. 2000);
b) The Short-Form McGill Pain Questionnaire (SF-MPQ) (Melzack, 1987);
c) The Life Line Stress Questionnaire (LL-SQ)(Burns, 1988:VIII-IX).

3.6.1 THE IBS-QOL

The IBS-QOL is a specific quality-of-life measure for IBS. Because there are no biological markers to assess IBS, and because a combination of socioeconomic, environmental and behavioral factors are important in examining the cause and outcome of this disease, it is important to evaluate their overall impact from the patients' perspective. The IBS-QOL does this. It has been tested for validity, as well as responsiveness to treatment (Drossman, et al. 2000).

3.6.2 The SF-MPQ

The SF-MPQ consists of 15 descriptors. Descriptors 1-11 represent the sensory dimension of pain experience and descriptors 12-15 represent the affective dimension. The overall pain score is represented by combining the sensory and affective dimensions of pain. Each descriptor is ranked on an intensity scale of Zero=none, 1=mild, 2=moderate and 3=severe. Present pain intensity (PPI) and the visual analogue scale (VAS) are also included to provide overall intensity scores (Melzack, 1987).

The use of the SF-MPQ, along with confirmation of its reliability, consistency and validity is provided by Melzack and Katz (1992).

3.6.3 The LLSQ

The LLSQ was used to monitor the patients' stress levels during the study period, as stress may play an important role in exacerbating the symptoms associated with IBS (Bennett, et al. 1998). Although this questionnaire has not been tested for reliability or validity, it has been found to be very useful by the Life Line organization, who use it extensively in their own work. This questionnaire is an adaptation of the questionnaire compiled by Burns (1988, VIII-IX).

3.6.4 Statistical Analysis of the Data.

Once all the data was collected it was treated as follows:

1) Each questionnaire was screened in order to determine if it had been completed correctly.
2) Scores obtained from each of the three questionnaires were expressed as percentages and recorded separately for the control and experimental groups.
3) The data then underwent statistical analysis.

3.7 STATISTICAL ANALYSIS

3.7.1 Treatment of the Data

Statistical analysis was done via non-parametric methods. Intra-group analysis was done using Friedman's T-Test or Wilcoxon's Signed rank test (depending on the number of measurements taken) and inter-group analysis was done using the Mann-Whitney-U test

All tests were done at the 5% level of significance (i.e. α=0.05).

3.7.2 Friedman's T-Test

Friedman's t-test was utilised for intra-group comparison. The decision rule was as follows:
Ho: The three treatments yielded identical results.
H_1: At least one treatment yielded larger values than at least one other treatment.
If $p<0.05$, the null hypothesis was rejected.

In the case of the null hypothesis being rejected the Dunn procedure (Multiple comparison procedure) was carried out to assess the effect of each treatment.

The formula utilised was as follows:
Let Rj and Rj' be the jth and j'th rank totals. Let $\propto$ be the experimental error rate.

If $|Rj-Rj'| > z\frac{bk(k+1)}{6}$, then Rj and Rj' were declared significant.

In the above formula: b=number of blocks

K=the number of treatments

Z=value in the inverse nomal distribution corresponding to $(1-[\alpha/k(k-1)])$

When K=3, α=0.10, Z=2.12

3.7.3 Mann-Whitney U Test

This test was used to make comparisons between the 4 experimental groups, which were treated as being independent of one another at consultations 1, 3 & 5.

Hypothesis test and Decision Rule:

H_0 : There was no difference between the two groups.

H_1 : There was a difference between the two groups.

H_0 stated that there was no difference between the 2 groups at consultations 1, 3 and 5.

H_1 stated that there was a difference between the two groups at treatment 1, 3 and 5.

α = 0.05 = level of significance

For a two-tailed test:

Reject if: $P < \alpha$

Accept if: $P > \alpha$

Note P is the observed significance level.

3.7.4 Wilcoxon's Signed Rank Test

The Wilcoxon Signed Rank Test shows any improvement from first to final measurement within a group (i.e. treatment 1 and 5).

Hypothesis Test and the Decision Rule

H_0 : There was no improvement between the treatments.

H_1 : There was an improvement between the treatments.

H0 (null hypothesis) stated that there was no improvement between treatments 1and 5.

H1 (alternative hypothesis) stated that there was an improvement between treatment 1 and 5.

P-value for a one-tailed test:

a) $P = \frac{\text{reported p-value}}{2}$ if

1) H_0 is of form > and Z is positive
2) H_1 is of form < and Z is negative

b) $P = 1 - \frac{(\text{reported p-value})}{2}$ if

1) H_0 is of form > and Z is negative
2) H_1 is of form < and Z is positive

P was the observed significance level.

3.8 SUMMARY STATISTICS

The summary statistics include the mean, standard deviation and standard error to support the result from the Wilcoxon Signed Rank Test, Mann-Whitney U Test, and Friedman's T-Tests.

If the statistical tests calculated a significant difference between the groups, the mean was used to identify the superior group. The reliability of the mean was measured using the standard deviation, which measures the spread of data around the mean. The larger the value, the larger spread of values and hence the less reliable the data. The standard error was used to measure the reliability of the mean used in statistical tests.

3.9 VISUAL REPRESENTATION OF THE DATA

Tables will be constructed to represent the major findings of the study, giving summary to results obtained from Friedmans T-Test, the Wilcoxon Signed Rank test and Mann-Whitney U tests. Tables will be constructed using Microsoft Word 97 SR-1 software package. The demographics data used from the patients files will be displayed using tables produced in Microsoft Excel. The statistical package SPSS will be used for data entry and analysis

CHAPTER FOUR

4.0 RESULTS

4.1 Introduction

This chapter concerns itself with the results obtained after statistical analysis of the data from the measurement criteria as discussed in chapter 3. This data is presented in table form with relevant comments and interpretations in order to accept or reject the null hypothesis.

A total of 64 subjects were recruited into the study. Sixty of these original 64 subjects completed the clinical trial. Two of the 4 subjects who failed to complete the trial cited work commitments as reasons. Of the remaining two dropouts, one patient felt uncomfortable receiving electrical therapy, in the fear that it could possibly make her symptoms worse, and the other patient withdrew due to inadequate transport arrangements.

4.2 ALLOCATION OF THE TREATMENT GROUPS

Table 4.1 Allocation of treatment groups

Group	Area of electrode placement	Placebo or active APT
A	Abdomen	Active
B	Abdomen	Placebo
C	Paraspinal	Active
D	Paraspinal	Placebo

4.3 DEMOGRAPHIC DATA

4.3.1 Age

Table 4.2 Age Distribution in Study Sample (N=60)

AGE INTER-VAL	GROUP A (n=15)		GROUP B (n=15)		GROUP C (n=15)		GROUP D (n=15)		TOTAL	
	No.	%	No.	%	No.	%	No.	%	No	%
20-29	5	33.3	3	20.0	3	20.0	4	26.7	15	25
30-39	4	26.7	7	47.7	8	53.3	5	33.3	24	40
40-49	5	33.3	2	13.3	2	13.3	2	13.3	11	18
50-59	1	6.7	0	0.0	0	0.0	1	6.7	2	3
60-69	0	0.0	3	20.0	2	13.3	3	20.0	8	13

The average age (mean) for group A was 35

The average age (mean) for group B was 40

The average age (mean) for group C was 39

The average age (mean) for group D was 43

4.3.2 Gender

Table 4.3 Gender Distribution in Study Sample (n=60)

GENDER	GROUP A (n=15)	GROUP B (n=15)	GROUP C (n=15)	GROUP D (n=15)
	No.	No.	No.	No.
MALE	5	12	12	12
FEMALE	10	3	3	3

The overall Female:Male Ratio was 2:2:1.

4.3.3 Race

Table 4.4 Race Distribution in Study Sample (n=60)

RACE	GROUP A (n=15)		GROUP B (n=15)		GROUP C (n=15)		GROUP D (n=15)	
	No.	%	No.	%	No.	%	No.	%
AFRICAN	0	0	0	0	0	0	0	0
INDIAN	6	40	3	20	3	20	3	20
COLOURED	1	6.7	0	0	0	0	1	6.7
WHITE	8	53.3	12	80	12	80	11	73.3

4.4 INTRA-GROUP COMPARISON

4.4.1 Group A (active APT, abdominal placement)

4.4.1.1 The IBS-Quality of Life Questionnaire

Friedman's t-test was utilised for intra-group comparison. The decision rule was as follows:

H_0: The three treatments yield identical results.

H_1: At least one treatment tends to yield larger values than at least one other treatment.

If $p<0.05$, reject the null hypothesis.

Table 4.5 Friedman T-Test for the IBS-QOL for group A.

Reading	Mean Rank	Rank Total
1	2.83	42.45
2	2.10	31.5
3	1.07	16.05

N	15
Chi-Square	24.034
Df	2
p-value	0.00

The Friedman T-test for the IBS-QOL for group 1 revealed a p-value of <0.01. As a result the null hypothesis was rejected (at the $\propto$=0.05 level of significance). This suggests that there was an over all improvement in the patient's perception of quality of life in group A.

As a result of the null hypothesis being rejected the Dunn procedure (Multiple comparison procedure) was carried out to assess the effect of each treatment.

The formula utilised was as follows:
Let R*j* and R*j'* be the jth and j'th rank totals. Let $\propto$ be the experimental error rate.

If $|Rj-Rj'| > z\frac{bk(k=1)}{6}$, then Rj and Rj' are declared significant.

In the above formula: b=number of blocks
K=the number of treatments
Z=value in the inverse nomal distribution corresponding to $(1-[\propto/k(k-1)])$

If k=3, Z=2.12.

If $|Rj-Rj'| > 11.61$, then Rj and Rj' are declared significantly different.

Results of this procedure:

Note: R1 represents the reading taken at the first consultation, before the 1st treatment.
R2 represents the reading taken at the third consultation, before the 3rd treatment.
R3 represents the reading taken at the final follow-up consultation, taken a week after the 4th treatment.

|R1-R2| = 42.45- 31.5=10.95<11.61 (ie.R1 and R2 are not different.)
|R1-R3| = 42.45- 16.05=26.40>11.61 (ie.R1 and R3 are different.)
|R2-R3| = 31.5- 16.05=15.45>11.61 (ie.R2 and R3 are different.)

The results of the Dunn procedure suggest, that in the experimental group, there was an improvement in the patients' quality of life (IBS-QOL) between the 2nd and 3rd readings and overall. No improvement seems to be evident after the 1st reading.

This suggests that the most of the therapeutic effect occurred after the 3rd and 4th treatments (these were the treatments that occurred between the 2nd and 3rd readings i.e. R2 and R3).

4.4.1.2 The Short-Form McGill Pain Questionnaire

Friedman's T-test was utilised for intra-group comparison. Data was analysed at the α=0.05 level of significance. The null hypothesis (H_0), the alternate hypothesis (H_1), and the decision rule were the same as that stated on page 27.

Table 4.6 Friedman T-test for the McGill Pain Questionnaire group A.

Reading	Mean Rank	Rank Total
1	2.87	42.45
2	2.00	31.5
3	1.13	16.05

N	15
Chi-Square	22.533
Df	2
p-value	<0.01

The Friedman T-test for the SF-MPQ for group 1 revealed a p-value of <0.01. As a result the null hypothesis was rejected (at the α=0.05 level of significance). This suggests that there was an overall improvement in the patient's perception of the quantity of pain in group A.

As a result of the null hypothesis being rejected the Dunn procedure (Multiple comparison procedure) was carried out to assess the effect of each treatment.

The formula was the same as that used on page 28.

If $|Rj-Rj'| > 11.61$, then Rj and Rj' are declared significantly different.

Results of this procedure:

| R1-R2| = 43.05- 30.00=13.05>11.61 (ie.R1 and R2 are different.)

| R1-R3| = 43.05- 16.95=26.10>11.61 (ie.R1 and R3 are different.)

| R2-R3| = 30.00- 16.95=13.05>11.61 (ie.R2 and R3 are different.)

The results of the Dunn procedure suggest, that in the experimental group, there was an improvement in the patients' perception of the quantity of pain between 1st and 2nd, and 2nd and 3rd readings, and overall. This suggests that similar therapeutic effect occurred after the 1st and 2nd treatments to 3rd and 4th treatments.

4.4.1.3 The Life-Line Stress Questionnaire

The Wilcoxon Signed Rank Test was used when analysing the LL-SQ because only two readings were taken, i.e. before the first consultation, and at the final follow-up consultation.

Table 4.7 Wilcoxon Signed Rank Test for the Life-Line Stress Questionnaire Group A

	Reading 1		Reading 2		
	Mean	S.D.	Mean	S.D.	P-Value
LL-SQ	27.067	9.004	24.133	8.717	0.123

These results compare the first and final readings of the LL-SQ for Group A. They indicate that at the 5% level of significance there was no improvement between the first and final readings.

4.4.2 Group B (placebo APT, abdominal placement)

4.4.2.1 The IBS-Quality of Life Questionnaire

Friedman's t-test was utilised for intra-group comparison. The null hypothesis (H_0), the alternate hypothesis (H_1), and the decision rule were the same as that stated on page 27.

Table 4.8 Friedman T-Test for the IBS-QOL for group B.

Reading	Mean Rank	Rank Total
1	2.50	37.5
2	1.90	28.5
3	1.60	24.0
N	15	
Chi-Square	6.407	
Df	2	
p-value	0.041	

The Friedman T-test for the IBS-QOL for group 1 revealed a p-value of 0.041. As a result the null hypothesis was rejected (at the $\propto$=0.05 level of significance). This suggests that there was an overall improvement in the patient's perception of quality of life in group B.

As a result of the null hypothesis being rejected the Dunn procedure (Multiple comparison procedure) was carried out to assess the effect of each treatment.

The formula was the same as that used on page 28.

If $|Rj-Rj'| > 11.61$, then Rj and Rj' are declared significantly different.

Results of this procedure:

Note: R1 represents the reading taken at the first consultation, before the 1st treatment.
R2 represents the reading taken at the third consultation, before the 3rd treatment.
R3 represents the reading taken at the final follow-up consultation, taken a week after the 4th treatment.

$|R1-R2| = 37.5- 28.5=9 < 11.61$ (ie.R1 and R2 are not different.)
$|R1-R3| = 37.5-24=13.5 > 11.61$ (ie.R1 and R3 are different.)
$|R2-R3| = 28.5-24=3 < 11.61$ (ie.R2 and R3 are not different.)

The results of the Dunn procedure suggest, that in the placebo group, there was an improvement in the patients' quality of life (IBS-QOL) only when comparing the first to last readings. No improvement seems to be evident individually between R1 and R2, or between R2 and R3. This suggests that the therapeutic effect occurred evenly from 1st to 3rd readings

4.4.2.2 The Short-Form McGill Pain Questionnaire

Friedman's T-test was utilised for intra-group comparison. Data was analysed at the α=0.05 level of significance. The null hypothesis (H_o), the alternate hypothesis (H_1), and the decision rule were the same as that stated on page 27.

Table 4.9 Friedman T-test for the McGill pain questionnaire group B.

Reading	Mean Rank	Rank Total
1	2.53	37.95
2	1.73	25.95
3	1.73	25.95

N	15
Chi-Square	7.680
Df	2
p-value	0.021

The Friedman T-test for the SF-MPQ for group B revealed a p-value of 0.021. As a result the null hypothesis was rejected (at the α=0.05 level of significance). This suggests that there was an overall improvement in the patient's perception of the quantity of pain in group B.

As a result of the null hypothesis being rejected the Dunn procedure (Multiple comparison procedure) was carried out to assess the effect of each treatment.

The formula was the same as that used on page 28.

If $|Rj-Rj'| > 11.61$, then Rj and Rj' are declared significantly different.

Results of this procedure:

$|R1-R2| = 37.95- 25.95= 12>11.61$ (ie.R1 and R2 are different.)

$|R1-R3| = 37.95- 25.95= 12>11.61$ (ie.R1 and R3 are different.)

$|R2-R3| = 25.95- 25.95= 0<11.61$ (ie.R2 and R3 are not different.)

The results of the Dunn procedure suggest, that in the placebo group, there was an improvement in the patients' perception of the quantity of pain between R1 and R2 and overall. No improvement is evident after the second reading. This suggests that greater therapeutic effect occurred after the 1st and 2nd treatments to after the 3rd and 4th treatments.

4.4.2.3 The Life-Line Stress Questionnaire

Table 4.10 Wilcoxon Signed Rank Test for the Life-Line Stress Questionnaire Group B

	Reading 1		Reading 2		
	Mean	S.D.	Mean	S.D.	P-Value
LL-SQ	23.267	9.4753	23.533	8.4504	0.874

These results compare the first and final readings of the LL-SQ for Group B. They indicate that at the 5% level of significance there was no improvement between the first and final readings.

4.4.3 Group C (active APT, paraspinal placement)

4.4.3.1 The IBS-Quality of Life Questionnaire

Friedman's t-test was utilised for intra-group comparison. The null hypothesis (H_0), the alternate hypothesis (H_1), and the decision rule were similar to that stated on page 27.

Table 4.11 Friedman T-Test for the IBS-QOL for group C.

Reading	Mean Rank	Rank Total
1	3.00	45.0
2	1.73	25.95
3	1.27	19.05

N	15
Chi-Square	24.133
Df	2
p-value	<0.01

The Friedman T-test for the IBS-QOL for group 1 revealed a p-value of <0.01. As a result the null hypothesis was rejected (at the $\propto$=0.05 level of significance). This suggests that there was an overall improvement in the patient's perception of quality of life in group C.

As a result of the null hypothesis being rejected the Dunn procedure (Multiple comparison procedure) was carried out to assess the effect of each treatment.

The formula was the same as that used on page 28.

If $|Rj-Rj'| > 11.61$, then Rj and Rj' are declared significantly different.

Results of this procedure:

Note: R1 represents the reading taken at the first consultation, before the 1st treatment.
R2 represents the reading taken at the third consultation, before the 3rd treatment.
R3 represents the reading taken at the final follow-up consultation, taken a week after the 4th treatment.

$|R1-R2| = 45-25.95=19.05 > 11.61$ (ie.R1 and R2 are different.)
$|R1-R3| = 45-19.05=15.95 > 11.61$ (ie.R1 and R3 are different.)
$|R2-R3| = 25.95-19.05=6.9 < 11.61$ (ie.R2 and R3 are not different.)

The results of the Dunn procedure suggest, that in the experimental group, there was an improvement in the patients quality of life (IBS-QOL) between the 1st and 2nd readings and overall. No improvement seems to be evident between the 2nd and 3rd reading. This suggests that the most of the therapeutic effect occurred after the 1st and 2nd treatments (these were the treatments that occurred between the 1st and 2nd readings).

4.4.3.2 The Short-Form McGill Pain Questionnaire

Friedman's T-test was utilised for intra-group comparison. Data was analysed at the α=0.05 level of significance. The null hypothesis (H_0), the alternate hypothesis (H_1), and the decision rule were the same as that stated on page 27.

Table 4.12 Friedman T-test for the McGill pain questionnaire group C.

Reading	Mean Rank	Rank Total
1	2.83	42.45
2	1.73	28.50
3	1.73	19.05
N	15	
Chi-Square	19.614	
Df	2	
p-value	<0.01	

The Friedman T-test for the SF-MPQ for group B revealed a p-value of <0.01. As a result the null hypothesis was rejected (at the α=0.05 level of significance). This suggests that there was an overall improvement in the patient's perception of the quantity of pain in group C.

As a result of the null hypothesis being rejected the Dunn procedure (Multiple comparison procedure) was carried out to assess the effect of each treatment.

The formula was the same as that used on page 28.

If $|Rj-Rj'| > 11.61$, then Rj and Rj' are declared significantly different.

Results of this procedure:

|R1-R2| = 42.45-28.5=13.95>11.61 (ie.R1 and R2 are different.)

|R1-R3| = 42.45-19.05=13.40>11.61 (ie.R1 and R3 are different.)

|R2-R3| = 28.5-19.05=9.45<11.61 (ie.R2 and R3 are not different.)

The results of the Dunn procedure suggest, that in the experimental group, there was an improvement in the patients' perception of the quantity of pain between the 1st and 2nd readings and overall. No improvement is evident between the 2nd and 3rd readings. This suggests that greater therapeutic effect occurred after the 1st and 2nd treatments to after the 3rd and 4th treatments.

4.4.3.3 The Life-Line Stress Questionnaire

Table 4.13 Wilcoxon Signed Rank Test for the Life-Line Stress Questionnaire Group C

	Reading 1		Reading 2		
	Mean	S.D.	Mean	S.D.	P-Value
LL-SQ	24.400	9.650	22.267	8.102	0.089

These results compare the first and final readings of the LL-SQ for Group C. They indicate that at the 5% level of significance there was no improvement between the first and final readings.

4.4.4 Group D (placebo APT, paraspinal placement)

4.4.4.1 The IBS-Quality of Life Questionnaire

Friedman's t-test was utilised for intra-group comparison. The null hypothesis (H_0), the alternate hypothesis (H_1), and the decision rule were the same as that stated on page 27.

Table 4.14 Friedman T-Test for the IBS-QOL for group D.

Reading	Mean Rank	Rank Total
1	2.60	39.0
2	1.87	28.05
3	1.53	22.95

N	15
Chi-Square	9.241
Df	2
p-value	0.01

The Friedman T-test for the IBS-QOL for group D revealed a p-value of 0.01. As a result the null hypothesis was rejected (at the α=0.05 level of significance). This suggests that there was an overall improvement in the patient's perception of quality of life in group D.

As a result of the null hypothesis being rejected the Dunn procedure (Multiple comparison procedure) was carried out to assess the effect of each treatment.

The formula was the same as that used on page 28.

If $|Rj-Rj'| > 11.61$, then Rj and Rj' are declared significantly different.

Results of this procedure:

Note: R1 represents the reading taken at the first consultation, before the 1st treatment.

R2 represents the reading taken at the third consultation, before the 3rd treatment.

R3 represents the reading taken at the final follow-up consultation, taken a week after the 4th treatment.

$|R1-R2| = 39-28.05=10.95 < 11.61$ (ie.R1 and R2 are not different.)

$|R1-R3| = 39-22.95=16.95 > 11.61$ (ie.R1 and R3 are different.)

$|R2-R3| = 28.05-22.95=5.1 < 11.6$ (ie.R2 and R3 are not different.)

The results of the Dunn procedure suggest, that in the placebo group, there was an improvement in the patients' quality of life (IBS-QOL) only when comparing the first to last

readings. No improvement seems to be evident individually between the 1st and 2nd, and 2nd and 3rd readings. This suggests that the therapeutic effect occurred evenly from 1st to 3rd readings

4.4.4.2 The Short-Form McGill Pain Questionnaire

Friedman's T-test was utilised for intra-group comparison. Data was analysed at the α=0.05 level of significance. The null hypothesis (H_0), the alternate hypothesis (H_1), and the decision rule were the same as that stated on page 27.

Table 4.15 Friedman T-test for the McGill pain questionnaire group D.

Reading	Mean Rank	Rank Total
1	2.77	41.55
2	1.83	27.45
3	1.40	21.00

N	15
Chi-Square	15.404
Df	2
p-value	<0.001

The Friedman T-test for the SF-MPQ for group B revealed a p-value of <0.01. As a result the null hypothesis was rejected (at the α=0.05 level of significance). This suggests that there was an overall improvement in the patient's perception of the quantity of pain in group D.

As a result of the null hypothesis being rejected the Dunn procedure (Multiple comparison procedure) was carried out to assess the effect of each treatment.

The formula was the same as that used on page 28.

If $|Rj-Rj'| > 11.61$, then Rj and Rj' are declared significantly different.

Results of this procedure:

$|R1-R2| = 41.55-27.45=14.1>11.61$ (ie.R1 and R2 are different.)

$|R1-R3| = 41.55-21=20.55>11.61$ (ie.R1 and R3 are different.)

$|R2-R3| = 27.45-21=6.45<11.61$ (ie.R2 and R3 are not different.)

The results of the Dunn procedure suggest, that in the placebo group, there was an improvement in the patients perception of the quantity of pain between the 1st and 2nd readings and overall. No improvement is evident between the 2nd and 3rd readings. This suggests that greater therapeutic effect occurred after the 1st and 2nd treatments to after the 3rd and 4th treatments.

4.4.4.3 The Life-Line Stress Questionnaire

Table 4.16 Wilcoxon Signed Rank Test for the Life-Line Stress Questionnaire Group D

	Reading 1		Reading 2		
	Mean	S.D.	Mean	S.D.	P-Value
LL-SQ	26.533	6.968	26.800	8.487	0.801

These results compare the first and final readings of the LL-SQ for Group D. They indicate that at the 5% level of significance there was no improvement between the first and final readings.

4.3 INTER-GROUP COMPARISON

4.3.1 The Mann-Whitney U Test comparing Group A to Group B

4.3.1.1 The IBS-QOL

Table 4.17 Results of the Mann-Whitney U Test comparing groups A and B with respect to the IBS-QOL.

Consultation	Group	Mean IBS-QOL value	P-value
1	A	97.467	0.372
	B	86.867	
5	A	65.667	0.494
	B	76.200	

The results indicate that at the α=0.05 level of significance, no difference was observed at consultations 1 and 5. As a result the null hypothesis is accepted for consultations 1 and 5. This suggests that there is no difference in improvement in quality of life between group A (i.e. active APT, abdominal placement), and group B (placebo APT, abdominal placement).

4.3.1.2 The SF-MPQ

Table 4.18 Results of the Mann-Whitney U Test comparing groups A and B with respect to the SF-MPQ.

Consultation	Group	Mean SF-MPQ value	P-value
1	A	51.267	0.787
	B	48.667	
5	A	24.800	0.304
	B	35.067	

The results indicate that at the α=0.05 level of significance, no difference was observed at consultations 1 and 5. As a result the null hypothesis is accepted for consultations 1 and 5.

This suggests that there is no difference in improvement of perceived pain between group A (i.e. active APT, abdominal placement), and group B (placebo APT, abdominal placement).

4.3.1.3 The LL-SQ

Table 4.19 Results of the Mann-Whitney U Test comparing groups A and B with respect to the LL-SQ.

Consultation	Group	Mean LL-SQ value	P-value
1	A B	27.067 23.267	0.299
5	A B	24.133 23.533	0.819

The results indicate that at the α=0.05 level of significance, no significant difference was observed at consultations 1 and 5. As a result the null hypothesis is accepted for consultations 1 and 5. This suggests that there is no difference in improvement of perceived stress between group A (i.e. active APT, abdominal placement), and group B (placebo APT, abdominal placement).

4.3.2 Group C compared to Group D

4.3.2.1 The IBS-QOL

Table 4.20 Results of the Mann-Whitney U Test comparing groups C and D with respect to the IBS-QOL.

Consultation	Group	Mean IBS-QOL value	P-value
1	C D	99.533 80.467	0.110
5	C D	74.267 63.533	0.237

The results indicate that at the α=0.05 level of significance, no significant difference was observed at consultations 1 and 5. As a result the null hypothesis is accepted for consultations 1 and 5. This suggests that there is no difference in improvement of quality of life between group C (i.e. active APT, paraspinal placement), and group D (placebo APT, paraspinal placement).

4.3.2.2 The SF-MPQ

Table 4.21 Results of the Mann-Whitney U Test comparing groups C and D with respect to the SF-MPQ.

Consultation	Group	Mean SF-MPQ value	P-value
1	C	64.867	0.040
	D	47.533	
5	C	32.800	0.802
	D	30.867	

The results indicate that at the α=0.05 level of significance, no significant difference was observed at consultation 5. At reading 1 (taken before the 1st consultation), there was an observed difference between groups C and D. This suggests that one group improved to a greater extent than the other. The mean pain score for group C was initially (at the first reading) higher than for group D. These results suggest that there was an improvement in the patients' perception of the quantity of pain experienced by patients in the paraspinally placed APT group, relative to the placebo group (also paraspinally placed). One may conclude then that APT placed paraspinally may have more of an effect than placebo on the patients' perception of the quantity of pain they experience, as a result of IBS.

4.3.2.3 The LL-SQ

Table 4.22 Results of the Mann-Whitney U Test comparing groups C and D with respect to the LL-SQ.

Consultation	Group	Mean LL-SQ value	P-value
1	C D	24.400 26.533	0.708
5	C D	22.267 26.800	0.119

The results indicate that at the α=0.05 level of significance, no difference was observed at consultations 1 and 5. As a result the null hypothesis is accepted for consultations 1 and 5. This suggests that there is no difference in improvement of perceived stress between group C (i.e. active APT, paraspinal placement), and group D (placebo APT, paraspinal placement).

4.3.3 Group A compared to Group C

4.3.3.1 The IBS-QOL

Table 4.23 Results of the Mann-Whitney U Test comparing groups A and C with respect to the IBS-QOL.

Consultation	Group	Mean IBS-QOL value	P-value
1	A C	97.467 99.533	0.787
5	A C	65.667 74.267	0.229

The results indicate that at the α=0.05 level of significance, no difference was observed at consultations 1 and 5. As a result the null hypothesis is accepted for consultations 1 and 5. This suggests that there is no difference in improvement of quality of life between group A (i.e. active APT, abdominal placement), and group C (active APT, paraspinal placement).

4.3.3.2 The SF-MPQ

Table 4.24 Results of the Mann-Whitney U Test comparing groups A and C with respect to the SF-MPQ.

Consultation	Group	Mean SF-MPQ value	P-value
1	A	51.267	0.046
	C	64.867	
5	A	24.800	0.381
	C	32.800	

The results indicate that at the α=0.05 level of significance, no significant difference was observed at consultation 5. At reading 1 (taken before the 1st consultation), there was an observed difference between groups A and C. This suggests that one group improved to a greater extent than the other. The mean pain score for group C was initially (at the first reading) higher than for group A. These results suggest that there was an improvement in the patients' perception of the quantity of pain experienced by patients in the paraspinally placed APT group, relative to the abdominally placed APT group. One may conclude then that APT placed paraspinally may have more of an effect than abdominally placed APT on the patients' perception of the quantity of pain they experience, as a result of IBS.

4.3.3.3 The LL-SQ

Table 4.25 Results of the Mann-Whitney U Test comparing groups A and C with respect to the LL-SQ.

Consultation	Group	Mean LL-SQ value	P-value
1	A	27.067	0.506
	C	24.400	
5	A	24.133	0.383
	C	22.267	

The results indicate that at the α=0.05 level of significance, no significant difference was observed at consultations 1 and 5. As a result the null hypothesis is accepted for consultations 1 and 5. This suggests that there is no difference in improvement of perceived stress between group A (i.e. active APT, abdominal placement), and group C (active APT, paraspinal placement).

CHAPTER FIVE

5.0 DISCUSSION

5.1. Introduction

This chapter will discuss the results obtained in chapter 4. Results were obtained via three different subjective questionnaires, which serve to investigate changes in the following categories:

1. Quality of life affected by the symptoms of IBS (assessed by the IBS-QOL)
2. Abdominal pain (assessed by the SF-MPQ)
3. Stress levels during the study (monitored by the LLSQ)

5. 2 Demographic Data

Tables 4.23-4.25 provides break downs of the age, racial and gender demographics of the study.

According to Bennett and Plum (1996: 686), IBS is most common in early adulthood, i.e. the 3rd and 4th decades, but can also have an onset after the age of 45. Most of the patients in this study (65%) fell within the 20-39 age group, which is in accordance with these findings. There was a steady drop in number of patients in each advancing age group, except in the 60-69 age group, where the number increased. The large proportion of elderly people that live in close proximity to the clinic, and thus have greater exposure to advertising in the area could possibly be responsible for this.

Most of the participants were from the white population (i.e.72%) with only 25% and 3% belonging to the Indian and coloured populations respectively. This suggests that IBS is most common amongst the white population. These figures could have been biased by the method of advertising, the location of the Chiropractic day clinic and the lack of awareness of IBS in the previously disadvantaged communities of South Africa.

The American Gastroenterological Association (1997) reported a female:male ratio of 2:1. This study showed a similar gender distribution of 2,2:1. The slight difference may be due to the small sample size.

5.3. Intra-group analysis

Intra-group analysis examines the improvement in each group from the 1st reading, taken before the 1st consultation, to the 3rd reading, taken at the final follow-up consultation (5th consultation).

5.3.1 The IBS-QOL

Statistical data may be found in Tables 4.11, 4.14, 4.17 and 4.20. The results (using Friedman's T-Test) revealed significant improvements in all groups in terms of the IBS-QOL between the initial and final consultations. Both placebo groups (groups B and D) showed consistent improvement in symptoms. Group A (active APT placed over the abdomen) showed most improvement between 3rd and final consultations. Conversely, Group C (active APT placed paraspinally) improved mostly between initial and 3rd consultations.

Such an impressive placebo response (groups B and D) in IBS trials has been discussed by Klein (1988), and is the reason why definitive results in IBS trials are so difficult to attain. Patients tend to feel more at ease once they realise the relative benign nature of IBS (in comparison to organic bowel disease). As psychological stress has such a large influence on the severity of the disease, visiting a health care practitioner can vastly improve symptoms of IBS, regardless of the treatment offered.

It is unclear why the quality of life in groups A and C improved differently at different stages of the trial.

5.3.2 The SF-MPQ

Statistical results may be found in tables 4.12, 4.15, 4.18 and 4.21. The results revealed significant improvements in all groups in terms of the SF-MPQ between initial and final consultations. Group A showed the most even improvement in symptoms. Groups B, C and D all improved mostly between initial and 3rd consultations.

De Wet and Oosthuizen (1998) showed a consistent increase in leucine enkephalin (which modulates pain at spinal level) between treatments when APT electrodes were placed

paraspinally. This does not explain the uneven improvement in quantity of pain of group C, although pain regulation is not affected by endocrine mechanisms alone.

5.3.3 The LL-SQ

Statistical results may be found in tables 4.13, 4.16, 4.19 and 4.22. The results indicated that there was no change in stress levels, in all groups, between initial and final consultations. This was important to establish, because of the effect of stress on symptoms of IBS. If, hypothetically, one of the group's stress levels did lower, for whatever reason, results of the other subjective findings could have been influenced.

5.4 Inter-Group Analysis

Evaluation of the findings taken before the 1st consultation shows any variance in findings between the groups in terms of their original presentation. Comparison of the groups at reading 3, taken at the 5th consultation, provides information as to whether there is a difference in the outcome of the treatments for the different groups.

5.4.1 The IBS-QOL

Statistical data may be found in tables 4.2-4.10. Mann-Whitney U tests were used to compare the groups at initial and final consultations. Comparison of IBS-QOL indicates that at the α=0.05 level of significance, no significant difference was observed between groups A and B, groups C and D, and groups A and C. This would seem to suggest that APT has no greater effect than placebo in improving the patients' quality of life with regards to their bowel symptoms, nor does changing the placement of the electrodes seem to have any bearing in this regard.

Differences between groups may have been more evident with a larger sample size, increasing the power of the statistical tests.

5.4.2 The SF-MPQ

When comparing the second subjective measure, i.e. the SF-MPQ, at the α=0.05 level of significance, the null hypothesis was accepted when comparing initial and final readings of

group A to group B. However, there was a significant difference when comparing initial readings of group C to group D. This is possibly explained by the small sample size of 15.

There was no more statistically significant difference between these groups when the final reading was taken, indicating that one of the groups may have improved to a greater extent. Since group C had a greater mean at the initial reading, this group could have improved to a greater extent. This could be interpreted to mean that active APT placed paraspinally has a greater effect than placebo APT, in improving the patients' perspective of quantity of abdominal pain. It is unwise however to reach any definitive conclusion from these results, since the groups were different to begin with, added to the fact that only subjective measurements were taken, thus introducing patient bias.

Similar results were found when group A was compared to group C. The initial readings were significantly different, but the final readings were not. Since group C had a greater mean pain index to begin with, it may have improved to a greater extent than group A. This might indicate that paraspinal placement had a greater beneficial effect on the patients' perception of quantity of pain than abdominal placement. Once again it is difficult to draw any conclusions from these results for the same reasons discussed above.

The reasons for these differences could be related to pain regulatory hormones, found by De Wet and Oosthuizen (1998) to be affected to a larger extent than placebo, when APT is applied paraspinally. This could explain the difference between the active and placebo APT groups when placed paraspinally (groups C and D).

It is also possible that paraspinal placement of electrodes could have a direct effect on the nervous system (i.e. via neural pathways to the G.I.T.), but further research is needed to support this hypothesis.

There has been no research study to date that compares abdominal to paraspinal placement of APT, so it is difficult to decide whether the possible difference in findings has any relevance. The only study of any similarity was the one conducted by Sylvester, Kendall and Lennard-Jones (1986). In this study, TENS, which is another form of electrical therapy, was

given to 29 IBS patients to take home. The patients were given 3 options of electrode placement: abdominal, paraspinal and over acupuncture points.

The majority of patients (71%), that improved preferred the abdominal group, with 21% and 8% choosing the paraspinal and acupuncture sites respectively. As most of the pain of IBS is felt over the abdomen, it is not unlikely that patients would try this area first. For this reason it is impossible to properly compare their findings to the ones in this study.

5.4.3 The LL-SQ

With regards to the LL-SQ, no significant differences were found between the groups at initial and final readings. One may conclude then that APT has no greater effect on the patients' perceived stress levels when compared to placebo, or when comparing abdominal versus paraspinal electrode placement.

5.5. Study Limitations

5.5.1 Food Intolerance

There is a high prevalence of lactose malabsorption in IBS due to the fact that lactose malabsorption may induce abdominal symptoms indistinguishable from those of IBS. It is therefore suggested that a test for diagnosing lactose malabsorption must be included in further studies. (Vernia, et al. 1995).

5.5.2 Measures of Efficacy

Only subjective measures were used in this study. Klein (1988) stated that because there are no objective markers for IBS, the determination of efficacy in treatment trials can only be based on subjective measures.

IBS is associated with a wide variety of symptoms and alteration in gastrointestinal function. This makes it difficult to decide on which symptoms to focus on. An attempt has been made to address this issue by use of three separate questionnaires, namely the IBS-QOL, the SF-

MPQ and the LL-SQ. It is unclear, however, whether these questionnaires did in fact measure what they were meant to measure and did so consistently. Patients with IBS often have multiple components to their disorder and it is difficult to capture them all with discreet, specific questionnaires.

5.5.3 Definition of IBS

Problems of definition are particularly important and critical for a condition such as IBS, as there are no objective markers, and symptoms are highly variable. An attempt was made to select patients according to the most reliable criteria possible, i.e. the Rome criteria (Table 3.1).

5.5.4 Blinding

The placebo response in IBS may range from $\leq$ 20% to more than 70% (Klein 1988). This variability introduces the problem of an adequate placebo control. Patient blinding was attempted in this study by using a placebo APT device (the exact method was described in chapter 3).

In theory, blinding the researcher as to which APT device is functioning is plausible, as patients should not feel tingling due to the high frequency of APT. Unfortunately, some patients are more sensitive than others, and alert the researcher as soon as they feel a slight sensation. The researcher thus soon realized which APT device was functioning, and was no longer blinded.

5.5.5 Crossover Design

The use of a crossover design is very important in IBS trial design. Here patients are initially randomized to receive one treatment and then, after a predetermined interval, are switched to the alternate therapy (Klein, 1988). For example in this study, patients would receive 3 treatments with placebo APT, placed abdominally, then receive 3 treatments with active APT, placed paraspinally, and so on.

A major problem with the crossover design is the 'carry over' effect, i.e. the change in symptoms from therapy in one group could affect the patients' response to the next group.

Whether or not this problem may apply to trials using APT to treat IBS is the subject of further study.

CHAPTER 6

6.0 RECOMMENDATIONS AND CONCLUSIONS

6.1. Recommendations

The author of this dissertation suggests the following changes to the treatment protocol for anyone wanting to repeat the this study:

A larger sample size is recommended in order to obtain a better representative of the general population.

It is recommended that patients be matched between groups in terms of age, sex, occupation, duration of complaint, extent of pain and disability to ensure homogeneity.

Having someone else apply the treatment, who has limited knowledge of the disorder, could increase the validity of this study. Patients with IBS usually feel highly frustrated, helpless as well as vulnerable to other illnesses. Conversations with the researcher can put many of these issues to rest, increasing the placebo response. Although the researcher tried to treat patients in all groups the same, and specific dietary advice was only given after the last reading was taken, the researcher is of the opinion that the placebo response could have been less if there was less contact between researcher and subjects.

As discussed in chapter 5, the placebo response may be as high as 70%. This introduces the problem of adequate placebo control. This has been attempted by using de-activated APT devices but other methods are available, such as placebo pills or sham manipulation. Whether other methods would have been more suitable remains the subject of further evaluation.

Ensuring that the researcher remains blinded was another problem discussed in chapter 5. One way would be to ask the patients not to tell the researcher whether they feel sensations or not. This is not plausible because one patient might express unease when the sensation is felt, thus preventing the researcher from being blinded.

Objective measurements are vital in order to reach definitive conclusions. Mention has been made of monitoring rectal sensitivity using a balloon distension device. Rectal sensitivity has been found to be raised in patients with IBS. However, more research is needed to evaluate whether this measurement is accurate in mapping the course of the disease.

A baseline comparison was done at the 1st consultation in order to highlight any important differences between the 2 groups. A run-in period, where patients are monitored for a month without treatment, to determine whether the symptoms are improving regardless, would be more appropriate. This would increase the accuracy of the baseline before treatment commenced, which would facilitate a clearer interpretation of the results.

The 3 week trial period was chosen because of the variability of IBS symptoms over time. The length of this treatment trial could have been longer as it would seem that 2 months is a minimum length for treatment trials in IBS. Longer trials may add to the clinical relevance of the intervention.

Exact intervals between consultations should be stipulated i.e. although the treatment period was 2 weeks each individual patient's consultations varied in terms of intervals between visits.

6.2 Conclusions.

The purpose of this study was to investigate the efficacy of action potential therapy versus placebo, and the relative effect of abdominal versus paraspinal electrode placement, in the treatment of Irritable Bowel Syndrome.

Sixty patients were included in the study. They all underwent a case history, physical examination and an abdominal regional examination. They were then randomly allocated to one of four groups, namely active abdominal, placebo abdominal, active paraspinal, and placebo paraspinal electrode placements of APT.

All participants in the study received four treatments over a two week period with subjective measurements being taken before the 1st, and 3rd treatments, as well as a final measurement taken 1 week after the 4th treatment (i.e. three measurements overall).

For this particular sample, it is impossible to establish that APT is any more effective than placebo in the management of IBS. From the results I am tempted to argue that paraspinal placement of active APT electrodes had a greater effect on pain perception than both abdominal placement as well as placebo. However it is impossible to reach a definitive conclusion from this because the groups were not homogenous to begin with. This does not mean that APT treatment is ineffectual in treating IBS, and it is quite possible that with a larger sample size, ensuring homogeneity, the results would have shown significant differences between groups.

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APPENDIX A

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient:..... Date: .....

File # :..... Age : .....

Sex :..... Occupation:.....

Intern :.....Signature:.....

FOR CLINICIANS USE ONLY:

Initial visit

Clinician:..... Signature :.....

Case History:

Examination:

Previous: Current:

X-Ray Studies:

Previous: Current:

Clinical Path. lab:

Previous: Current:

Case Status:

PTT:.....

Signature:..... **Date:**.....

Conditional:

Reason for Conditional:.....

Signature: ..... **Date:** .....

All Conditions met in Visit No.:.....

To be signed into PTT:.....

Signature:..... **Date:** .....

Signed off:.....

Intern's Case History:

1. **Source of History:**

2. **Chief Complaint : (patient's own words):**

3. **Present Illness:**

	Complaint 1	Complaint 2
▹ Location		
▹ Onset : Initial:		
Recent:		
▹ Cause:		
▹ Duration		
▹ Frequency		
▹ Pain (Character)		
▹ Progression		
▹ Aggravating Factors		
▹ Relieving Factors		
▹ Associated S & S		
▹ Previous Occurrences		
▹ Past Treatment		
▹ **Outcome:**		

4. **Other Complaints:**

5. **Past Medical History:**

▹ General Health Status

▹ Childhood Illnesses

▹ Adult Illnesses

- Psychiatric Illnesses
- Accidents/Injuries
- Surgery
- Hospitalizations

6. Current health status and life-style:

- Allergies
- Immunizations
- Screening Tests incl. xrays
- Environmental Hazards (Home, School, Work)
- Exercise and Leisure
- Sleep Patterns
- Diet
- Current Medication
  Analgesics/week:
- Tobacco
- Alcohol
- Social Drugs

7. Immediate Family Medical History:

- Age
- Health
- Cause of Death
- DM
- Heart Disease
- TB
- Stroke
- Kidney Disease
- CA
- Arthritis
- Anaemia
- Headaches
- Thyroid Disease
- Epilepsy
- Mental Illness
- Alcoholism
- Drug Addiction
- Other

8. Psychosocial history:

- Home Situation and daily life
- Important experiences
- Religious Beliefs

9. Review of Systems:

- General
- Skin
- Head
- Eyes
- Ears
- Nose/Sinuses
- Mouth/Throat
- Neck
- Breasts
- Respiratory
- Cardiac
- Gastro-intestinal
- Urinary
- Genital
- Vascular
- Musculoskeletal
- Neurologic
- Haematologic
- Endocrine
- Psychiatric

APPENDIX B

TECHNIKON NATAL

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC

PHYSICAL EXAMINATION

Patient:_____File#: _____Date:_____
Clinician:_____Signature:_____
Intern:_____Signature:_____

1. VITALS

Pulse rate:
Respiratory rate:
Blood pressure: R L
Temperature:
Height:
Weight:

2. GENERAL EXAMINATION

General Impression:
Skin:
Jaundice:
Pallor:
Clubbing:
Cyanosis (Central/Peripheral):
Oedema:
Lymph nodes - Head and neck:
- Axillary:
- Epitrochlear:
- Inguinal:

Urinalysis:

3. CARDIOVASCULAR EXAMINATION

1) Is this patient in **Cardiac Failure** ?
2) Does this patient have signs of **Infective Endocarditis** ?
3) Does this patient have **Rheumatic Heart Disease ?**

Inspection - Scars
- Chest deformity:
- Precordial bulge:
- Neck -JVP:

Palpation: - Apex Beat (character + location):
- Right or left ventricular heave:
- Epigastric Pulsations:
- Palpable P2:
- Palpable A2:

Pulses:
- General Impression:
- Radio-femoral delay:
- Carotid:
- Radial:
- Dorsalis pedis:
- Posterior tibial:
- Popliteal:
- Femoral:

Percussion: - borders of heart

Auscultation: - heart valves (mitral, aortic, tricuspid, pulmonary)
- Murmurs (timing,systolic/diastolic, site, radiation, grade).

4. RESPIRATORY EXAMINATION

1) Is this patient in **Respiratory Distress** ?

Inspection
- Barrel chest:
- Pectus carinatum/cavinatum:
- Left precordial bulge:
- Symmetry of movement:
- Scars:

Palpation
- Tracheal symmetry:
- Tracheal tug:
- Thyroid Gland:
- Symmetry of movement (ant + post)
- Tactile fremitus:

Percussion
- Percussion note:
- Cardiac dullness:
- Liver dullness:

Auscultation
- Normal breath sounds bilat.:
- Adventitious sounds (crackles, wheezes, crepitations)
- Pleural frictional rub:
- Vocal resonance
  - Whispering pectoriloquy:
  - Bronchophony:
  - Egophony:

5. ABDOMINAL EXAMINATION

1) Is this patient in **Liver Failure** ?

Inspection
- Shape:
- Scars:
- Hernias:

Palpation
- Superficial:
- Deep = Organomegally:

- Masses (intra- or extramural)
- Aorta:

Percussion - Rebound tenderness:
- Ascites:
- Masses:

Auscultation - Bowel sounds:
- Arteries (aortic, renal, iliac, femoral, hepatic)

Rectal Examination
- Perianal skin:
- Sphincter tone & S4 Dermatome:
- Obvious masses:
- Prostate:
- Appendix:

6. G.U.T EXAMINATION

External genitalia:
Hernias:
Masses:
Discharges:

7. NEUROLOGICAL EXAMINATION

Gait and Posture
- Abnormalities in gait:
- Walking on heels (L4-L5):
- Walking on toes (S1-S2):
- Rombergs test (Pronator Drift):

Higher Mental Function
- Information and Vocabulary:
- Calculating ability:
- Abstract Thinking:

G.C.S.:
- Eyes:
- Motor:
- Verbal:

Evidence of head trauma:

Evidence of Meningism:
- Neck mobility and Brudzinski's sign:
- Kernigs sign:

Cranial Nerves:

I Any loss of smell/taste:
Nose examination:

II External examination of eye:
- Visual Acuity:
- Visual fields by confrontation:

- Pupillary light reflexes = Direct:
  = Consensual:
- Fundoscopy findings:

III Ocular Muscles:
Eye opening strength:

IV Inferior and Medial movement of eye:

V
a. Sensory - Ophthalmic:
- Maxillary:
- Mandibular:
b. Motor - Masseter:
- Jaw lateral movement:
c. Reflexes - Corneal reflex
- Jaw jerk

VI Lateral movement of eyes

VII
a. Motor - Raise eyebrows:
- Frown:
- Close eyes against resistance
- Show teeth:
- Blow out cheeks:
b. Taste - Anterior two-thirds of tongue:

VIII General Hearing:
Rinnes = L: R:
Webers lateralisation:
Vestibular function - Nystagmus:
- Rombergs:
- Wallenbergs:
Otoscope examination:

IX & X Gag reflex:
Uvula deviation:
Speech quality:

XI Shoulder lift:
S.C.M. strength:

XII Inspection of tongue (deviation):

Motor System:

a. Power
- Shoulder = Abduction & Adduction:
  = Flexion & Extension:
- Elbow = Flexion & Extension:
- Wrist = Flexion & Extension:

- Forearm = Supination & Pronation:
- Fingers = Extension (Interphalangeals & M.C.P's):
- Thumb = Opposition:
- Hip = Flexion & Extension:
  = Adduction & Abduction:
- Knee = Flexion & Extension:
- Foot = Dorsiflexion & Plantar flexion:
  = Inversion & Eversion:
  = Toe (Plantarflexion & Dorsiflexion):

b. Tone
- Shoulder:
- Elbow:
- Wrist:
- Lower limb - Int. & Ext. rotation:
- Knee clonus:
- ankle clonus:

c. Reflexes
- Biceps:
- Triceps:
- Supinator:
- Knee:
- Ankle:
- Abdominal:
- Plantar:

Sensory System:

a. Dermatomes
- Light touch:
- Crude touch:
- Pain:
- Temperature:
- Two point discrimination:

b. Joint position sense
- Finger:
- Toe:

c. Vibration:
- Big toe:
- Tibial tuberosity:
- ASIS:
- Interphalangeal Joint:
- Sternum:

Cerebellar function:

Obvious signs of cerebellar dysfunction:
= Intention Tremor:
= Nystagmus:
= Truncal Ataxia:

Finger-nose test (Dysmetria):
Rapid alternating movements (Dysdiadochokinesia):
Heel-shin test:
Heel-toe gait:
Reflexes:
Signs of Parkinsons:

8. SPINAL EXAMINATION:(See Regional examination)

Obvious Abnormalities:
Spinous Percussion:
R.O.M:
Other:

9. BREAST EXAMINATION:

Summon female chaperon.

Inspection
- Hands rested in lap:
- Hands pressed on hips:
- Arms above head:
- Leaning forward:

Palpation
- masses:
- tenderness:
- axillary tail:
- nipple:
- regional lymph nodes:

APPENDIX C

Rome Criteria (Drossman, et al. 1999)

At least 3 months of continuous or recurrent symptoms of the following:

Abdominal pain or discomfort,

- Relieved with defecation, or
- Associated with a change in frequency of stool, or
- Associated with a change in consistency of stool.

Two or more of the following, on at least one-fourth of occasions or days:

- Altered stool frequency (for research purposes, "altered" may be defined as more than three bowel movements each day or fewer than three bowel movements each week);
- Altered stool form (lumpy and hard, or loose and watery);
- Altered stool passage (straining, urgency or a feeling of incomplete evaluation);
- Passage of mucus, or

Bloating or a feeling of abdominal distention

APPENDIX D

PATIENT INFORMATION SHEET

Title: The efficacy of action potential therapy, as well as the relative effect of two different action potential therapy electrode placements (abdominal versus paraspinal) in the management of Irritable Bowel Syndrome.

Dear Participant

The aim of this research is to determine whether Action Potential Therapy has a therapeutic effect on Irritable Bowel Syndrome (IBS).

If you think you have IBS or have been previously diagnosed with this condition, you may be elected to take part in this study, which is free of charge. Once a diagnosis has been made, you will be placed into one of two groups. Both groups will receive action potential therapy for eight minutes at 0-2 milliamperes. One of these groups will, however, receive a sham treatment – you will therefore stand a 50-50 chance of being allocated to this group. Patients that received placebo treatment will be allowed four free treatments after their final consultation, which will also be free of charge.

The treatments used in this study have been shown to be safe and you should therefore not experience any unpleasant side-effects

All patients will be required to return for a maximum of four consultations over a two week period.

After the final treatment, important information will be made available to you regarding dietary modifications, life-style modifications and current medical management of this disease. Thus even if you have been treated in the placebo group, you will become better equipped on how to reduce your discomfort to a minimum.

Pregnant women will unfortunately be excluded from this study, as will patients who are on any prescription medication, other than the contraceptive pill. You are also urged to maintain your normal diet and lifestyle for the duration of the research. Other reasons you may be excluded are:

A.. If you are using a pacemaker.
B. If you suffer from epileptic seizures
C. If you are on anticoagulant medication
D. If you have been diagnosed with any form of cancer.
E. If you have any form of venous thrombosis.

Health information is intimate and private. That's why we take extra precaution to ensure that your privacy is protected. Rest assured that under no circumstances will confidentiality be breeched.

All treatment will be supervised by a qualified Chiropractor and you will be free to withdraw from this research at any time.

Thank you for your participation in this important research.

Yours sincerely

IVOR VON SENGER
(Masters Research Student)

APPENDIX E

INFORMED CONSENT FORM

(To be completed in duplicate by patient/subject)

TITLE OF RESEARCH PROJECT: The efficacy of action potential therapy, as well as the relative effect of two different action potential therapy electrode placements (abdominal versus paraspinal) in the management of Irritable Bowel Syndrome.

NAME OF SUPERVISOR: Dr. A van der Meulen

NAME OF RESEARCH STUDENT: Ivor von Senger

PLEASE CIRCLE THE APPROPRIATE ANSWER

1. Have you read the research information sheet? YES/NO

2. Have you had an opportunity to ask questions regarding this study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO

4. Have you had an opportunity to discuss this study? YES/NO
5. Have you received enough information about this study? YES/NO

6. Who have you spoken to? _____

7. Do you understand the implications of your involvement in this study? YES/NO

8. Do you understand that you are free to withdraw from this study? YES/NO
   a) at any time
   b) without having to give a reason for withdrawing, and
   c) without affecting your future health care?

9. Do you agree to voluntarily participate in this study? YES/NO

If you have answered no to any of the above, please obtain the information before signing.

PATIENT/ SUBJECT Name _____ Signature _____
(in block letters)

PARENT/ GUARDIAN Name _____ Signature _____
(in block letters)

WITNESS Name _____ Signature _____
(in block letters)

RESEARCH STUDENT Name _____ Signature _____
(in block letters)

APPENDIX F The IBS-Quality of Life Questionnaire.

Place a cross in the correct column.

	1.	2.	3.	4.	5.
1. I feel helpless because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
5. I am embarrassed by the smell caused by my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
6. I am bothered by how much time I spend on the toilet.	Not at all	Slightly	Moderately	Quite a bit	A great dea
7. I feel vulnerable to other illnesses because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
8. I feel fat because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	A great dea
9. I feel like I am losing control of my life because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	A great dea
10. I feel like my life is less enjoyable because of my bowel symptoms.	Not at all	Slightly	Moderately	Quite a bit	A great dea
11. I feel uncomfortable when I talk about my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
12. I feel depressed about my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
13. I feel isolated from others because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	A great de
14. I have to watch the amount of food I eat because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Not at all
15. Because of my bowel problems, sexual activity is difficult for me.	Not at all	Slightly	Moderately	Quite a bit	Extremely
16. I feel angry because I have bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
17. I feel like I irritate others because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	A great de
18. I worry that my bowel problems will get worse	Not at all	Slightly	Moderately	Quite a bit	A great de
19. I feel irritable because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
20. I worry that people think I exaggerate my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	A great de
21. I feel I get less done because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	A great de
22. I have to avoid stressful situations because of my bowel problems	Not at all	Slightly	Moderately	Quite a bit	A great d
23. My bowel problems reduce my sexual desire.	Not at all	Slightly	Moderately	Quite a bit	A great d
24. My bowel problems limit what I can wear.	Not at all	Slightly	Moderately	Quite a bit	A great d

	1.	2.	3.	4	5.
25. I have to avoid strenuous activity because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	A great de
26. I have to watch the kind of food I eat because of my bowel problems	Not at all	Slightly	Moderately	Quite a bit	A great de
27. Because of my bowel problems I have difficulty being around people I do not know well.	Not at all	Slightly	Moderately	Quite a bit	A great de
28. I feel sluggish because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
29. I feel unclean because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
30. Long trips are difficult for me because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
31. I feel frustrated because I cannot eat when I want because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
32. It is important for me to be near a toilet because of my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely
33. My life revolves around my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	A great dea
34. I worry about losing control of my bowels.	Not at all	Slightly	Moderately	Quite a bit	A great dea
35. I fear I won't be able to have a bowel movement.	Not at all	Slightly	Moderately	Quite a bit	A great dea
36. My bowel problems are affecting my closest relationships.	Not at all	Slightly	Moderately	Quite a bit	A great dea
37. I feel that no one understands my bowel problems.	Not at all	Slightly	Moderately	Quite a bit	Extremely

APPENDIX G

LIFE LINE PIETERMARITZBURG
STRESS QUESTIONNAIRE

ARE YOU UNDER STRESS?

Find out whether you are under stress by completing the questionnaire. Respond to each statement quickly; do not think too much about each one. Your first thought about the frequency of behaviour is usually the most accurate.

NO.	YOUR BEHAVIOUR	OFTEN	A FEW TIMES A MONTH	RARELY
1.	I have indigestion	2	1	0
2.	I have difficulty finding enough time to relax	2	1	0
3.	I smoke when I feel tense	2	1	0
4.	People at work make me feel tense	2	1	0
5.	I sleep badly	2	1	0
6.	I find it difficult to concentrate on what I am doing because I worry about other things	2	1	0
7.	I feel anxious	2	1	0
8.	I eat more when anxious	2	1	0
9.	I have headaches	2	1	0
10.	People at home make me feel tense	2	1	0
11.	I have aches & pains in my neck & shoulders	2	1	0
12.	Even if I find time to relax, it is hard for me to relax	2	1	0
13.	I drink when I feel tense	2	1	0
14.	My day is made up of deadlines	2	1	0
15.	I can't turn off my thoughts for long enough at night to feel refreshed the next day	2	1	0
16.	I take tranquillisers (or drugs) to relax	2	1	0
17.	I feel my heart beats fast	2	1	0
18.	My legs feel wobbly	2	1	0
19.	I perspire without even exercising	2	1	0
20.	I get angry/irritated quickly	2	1	0
21.	I am impatient and become frustrated with others	2	1	0
22.	I do things in a hurry	2	1	0
23.	I talk quickly	2	1	0
24.	I worry that there are so many things I can do nothing about	2	1	0
25.	I cannot sit still for long	2	1	0
	TOTAL			

SCORING:

30-50 = CONSIDERABLY ABOVE AVERAGE LEVEL OF STRESS
15-29 = ABOVE AVERAGE
10-14 = AVERAGE
5-9 = BELOW AVERAGE
0-4 = CONSIDERABLY BELOW AVERAGE

APPENDIX H

LIFE LINE PIETERMARITZBURG
STRESS QUESTIONNAIRE

ARE YOU UNDER STRESS?

Find out whether you are under stress by completing the questionnaire. Respond to each statement quickly; do not think too much about each one. Your first thought about the frequency of behaviour is usually the most accurate.

NO	YOUR BEHAVIOUR	OFTEN	A FEW TIMES A MONTH	RARELY
1.	I have indigestion	2	1	0
2.	I have difficulty finding enough time to relax	2	1	0
3.	I smoke when I feel tense	2	1	0
4.	People at work make me feel tense	2	1	0
5.	I sleep badly	2	1	0
6.	I find it difficult to concentrate on what I am doing because I worry about other things	2	1	0
7.	I feel anxious	2	1	0
8.	I eat more when anxious	2	1	0
9.	I have headaches	2	1	0
10.	People at home make me feel tense	2	1	0
11.	I have aches & pains in my neck & shoulders	2	1	0
12.	Even if I find time to relax, it is hard for me to relax	2	1	0
13.	I drink when I feel tense	2	1	0
14.	My day is made up of deadlines	2	1	0
15.	I can't turn off my thoughts for long enough at night to feel refreshed the next day	2	1	0
16.	I take tranquillisers (or drugs) to relax	2	1	0
17.	I feel my heart beats fast	2	1	0
18.	My legs feel wobbly	2	1	0
19.	I perspire without even exercising	2	1	0
20.	I get angry/irritated quickly	2	1	0
21.	I am impatient and become frustrated with others	2	1	0
22.	I do things in a hurry	2	1	0
23.	I talk quickly	2	1	0
24.	I worry that there are so many things I can do nothing about	2	1	0
25.	I cannot sit still for long	2	1	0
	TOTAL			

SCORING:

30-50	=	CONSIDERABLY ABOVE AVERAGE LEVEL OF STRESS
15-29	=	ABOVE AVERAGE
10-14	=	AVERAGE
5-9	=	BELOW AVERAGE
0-4	=	CONSIDERABLY BELOW AVERAGE